



Pipeline and Hazardous Materials Safety Administration

MAR 1 5 2005

DOT-E 13208 (THIRD REVISION)

EXPIRATION DATE: February 28, 2007

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE:

Provensis Limited of South Harefield South Harefield, Middlesex, United Kingdom (U.S. Agent: Provensis Inc., West Conshohocken, PA)

## 2. PURPOSE AND LIMITATION:

- a. This exemption authorizes the transportation in commerce of certain DOT Specification 2Q containers containing only a Division 2.2 material for use in medical treatment. This exemption provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein.
- b. The safety analyses performed in development of this exemption only considered the hazards and risks associated with transportation in commerce. The safety analyses did not consider the hazards and risks associated with consumer use, use as a component of a transport vehicle or other device, or other uses not associated with transportation in commerce.
- 3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.

- 4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 173.302a(a)(1) in that DOT Specification 2Q containers are not authorized for oxygen, compressed, except as specified herein; Part 172 Subpart C for carbon dioxide, unless transported by air; Part 172 Subpart E unless transported by air; Part 172 Subpart F; Part 174; and Part 177 except for § 177.817.
- 5. <u>BASIS</u>: This exemption is based on Provensis Limited's application dated February 23, 2005, submitted in accordance with § 107.109.

## 6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identi- fication Number	Packing Group
Carbon dioxide	2.2	UN1013	N/A
Oxygen, compressed	2.2	UN1072	N/A

## 7. SAFETY CONTROL MEASURES:

- a. <u>PACKAGING</u> Packagings prescribed are seamless DOT Specification 2Q containers not exceeding 500ml capacity and having a minimum burst pressure of 270 psig. Containers must be shipped as follows:
  - (1) The pressure in the container shall not exceed 75 psig at  $70^{\circ}F$  and 90 psig at  $130^{\circ}F$ .
  - (2) The containers must be packed in strong outside packagings.
  - (3) Each package shall not exceed 66 pounds gross weight.

- b. <u>TESTING</u> Each completed container filled for shipment must have been heated until the pressure in the container is equivalent to the equilibrium pressure of the content at 130°F without evidence of leakage, distortion, or other defect.
- c. OPERATIONAL CONTROLS Shipments of authorized devices containing carbon dioxide only, are not subject to the shipping paper requirements of Subpart C of Part 172 unless offered for transportation by air. Shipments are not subject to the labeling requirements of Subpart E of Part 172 unless offered for transportation by air. Shipments are not subject to the placarding requirements of Subpart F of Part 172; to Part 174 and to Part 177, except for § 177.817.

## 8. SPECIAL PROVISIONS:

- a. A person who is not a holder of this exemption who receives a package covered by this exemption may reoffer it for transportation provided no modifications or change are made to the package and it is reoffered for transportation in conformance with this exemption and the HMR.
- b. A current copy of this exemption must be maintained at each facility where the package is offered or reoffered for transportation.
- c. Each outer package must meet the marking requirements of Subpart D of Part 172 and be marked "DOT-E 13208".
- d. This exemption does not authorize reclassification as Consumer commodity, ORM-D.
- 9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle, rail freight, cargo vessel, and cargo aircraft only.
- 10. MODAL REQUIREMENTS: A current copy of this exemption must be carried aboard each aircraft used to transport packages covered by this exemption. The shipper must furnish a current copy of this exemption to the air carrier before or at the time the shipment is tendered. In addition, for shipments of authorized devices charged with oxygen:

- (1) A maximum of 20 packages of 20 authorized containers each may be carried aboard each aircraft.
- (2) Packages of authorized containers must not be loaded in an inaccessible cargo location on a cargo-only aircraft. Packages must be loaded in such a manner that a crew member or other authorized person can see, handle and when size and weight permit, separate such packages from other cargo during flight.
- 11. <u>COMPLIANCE</u>: Failure by a person to comply with any of the following may result in suspension or revocation of this exemption and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq:
  - o All terms and conditions prescribed in this exemption and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
  - o Persons operating under the terms of this exemption must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
  - o Registration required by § 107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this exemption must receive training on the requirements and conditions of this exemption in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this exemption, including display of its number, when this exemption has expired or is otherwise no longer in effect.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this exemption are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 - Immediate notice of certain hazardous materials incidents, and 171.16 - Detailed hazardous materials

incident reports. In addition, the grantee(s) of this exemption must notify the Associate Administrator for Hazardous Materials Safety -- OHMEA, in writing, of any incident involving a package, shipment or operation conducted under terms of this exemption.

Issued in Washington, D.C.:

Robert A. McGuire

MAR 1 5 2005

(DATE)

Associate Administrator for Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, Department of Transportation, Washington, D.C. 20590. Attention: DHM-31.

Copies of this exemption may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/exemptions. Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

PO: CWF/sln

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